REMARKS

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the remarks and amendments herein.

I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 27-39, 45 and 47 are now pending. Claims 27-32, 36-39, 45 and 47 have been amended, and claims 1-26, 40-44 and 46 have been cancelled, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is respectfully submitted that these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments to the claims and the remarks herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather the amendments and remarks are made simply to place the claims in better condition for examination.

II. INFORMATION DISCLOSURE STATEMENT

The Office Action refers to an Information Disclosure Statement submitted on February 28, 2007. Applicants believe that the Information Disclosure Statement to which the Office Action intended to refer was filed September 30, 2003. The Office Action indicates that it was not possible to determine the relevance of sequences referred to by Accession numbers without appropriate comparisons. Applicants respectfully submit that the cited documents have no significant similarity to the SEQ ID Nos. 1-3, as are recited in the claims. However, if required, Applicants can submit alignments documenting the lack of identity.

The Office Action also indicates that the reference Jobling et al. (2001) was missing from the file and therefore not considered. Applicants will provide a copy of the reference under separate cover.

III. THE OBJECTION TO THE SPECIFICATION IS OVERCOME

The Office Action indicated that the specification was objected to for failing to contain the application's priority information on the first line of the application. Applicants respectfully assert that page i (before page 1) of the present application as filed contains the priority

information as required. Applicants have reviewed the file history on PAIR for the present application, and believe that page i may be missing from the electronic file wrapper. Accordingly, Applicants have amended the application herein to add the text of page i to the application. Furthermore, Applicants respectfully submit that no new matter is added by this amendment as the text that is the basis of the amendment was present in the application at the time of filing.

Appendix A, attached hereto, contains a copy of the return-receipt postcard which indicates that 40 pages of application were provided to the Patent Office. As the Patent Office did not amend this text on the postcard prior to returning the postcard to Applicants, the Patent Office has indicated that 40 pages of application were received. Also attached are the Utility Transmittal which accompanied the application, which again indicates that the application contained 40 pages. A full copy of the application as filed is also attached. Applicants note that the application is numbered pages i, 1-39, for a total of 40 pages. Thus, page i was received by the Patent Office at the time the application was filed, such that the present amendment is not new matter.

Consequently, entry of the amendment to the specification and reconsideration and withdrawal of the objection to the specification is respectfully requested.

IV. THE SEQUENCE REQUIREMENTS ARE MET

The Office Action indicated that the present application failed to comply with the requirements of 37 CFR 1.821 to 1.825 because "a SEQ ID NO: and sequence listing is required for the peptide sequence listed in claim 47."

Applicants respectfully submit that claim 47 has been amended herein to include reference to SEQ ID NO: 3. It is also noted that SEQ ID NO: 3 is present in the Sequence Listing filed May 25, 2004, such that it is believed no further Sequence Listing is required at this time.

Consequently, reconsideration and withdrawal of the objection to the application for failure to comply with the sequence requirements is respectfully requested.

V. THE OBEJCTIONS TO THE CLAIMS ARE OVERCOME

Claims 37-39 were objected to under 37 CFR 1.75(c) as allegedly being in improper form because a multiply dependent claim cannot be dependent from another multiply dependent claim. The objection is respectfully traversed.

Applicants have amended the claims herein to remove the improper multiple dependencies. Thus, the objection is now moot.

Consequently, reconsideration and withdrawal of the objection to the claims is respectfully requested.

VI. THE REJECTIONS UNDER 35 USC §112 ARE OVERCOME

Claim 45 was rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement for a pharmaceutical composition for the treatment of any disease or condition. The rejection is respectfully traversed.

As currently pending, claim 45 relates to a pharmaceutical composition comprising a peptide selected from SEQ ID NO: 1-3 or a functional variant thereof which is at least 80% identical to SEQ ID NO: 1-3 and which retains its ability to bind to a causative agent of a disease or a disorder, said causative agent having SOD activity, and inhibit the causative agent's SOD and/or metal binding ability and a pharmaceutically acceptable carrier or diluent

35 U.S.C. §112, first paragraph, requires that the specification describe how to make and use the invention. 35 U.S.C. §112, first paragraph, recites, in pertinent part:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same[.]

A patent claim is invalid if it is not, *inter alia*, supported by an enabling disclosure. The test for enablement requires a determination of whether any person skilled in the art can make and use the invention without undue experimentation. *See In re Wands*, 858 F.2d 731, 8 U.S.P.Q.2d 1400, (Fed. Cir. 1988). The factors involved in determining whether there is sufficient evidence to support a finding of enablement include, among others, (1) the breadth of the claims, (2) the nature of the invention, (3) the state of the prior art, (4) the level of one of ordinary skill, (5) the level of predictability in the art, (6) the amount of direction provided by the inventor, (7) the existence of working examples, and (8) the quantity of experimentation needed

to make or use the invention based on the content of the disclosure. *See Wands*, 858 F.2d at 737, 8 U.S.P.Q.2d at 1404.

Initially, the Office Action admits that enablement is present for making the polypeptide of SEQ ID NO: 3 that binds Aβ. The Office Action then indicates that the present invention relates to "a peptide of SEQ ID NO: 3 that binds to Aβ….its effective use for treatment of any disease is complex, because SEQ IDN O: 3 is derived from a method of merely identifying candidate peptides for treatment….peptide[s] may or may not be effective at treating any one of myriad diseases linked to SOD activity." Office Action at 4. Applicants respectfully disagree with this assertion, especially in view of the remarks and amendments herein.

Claim 45 recites a pharmaceutical composition comprising the polypeptide of claim 27. Claim 27 has been amended herein to specify that the claimed polypeptide has the sequence of SEQ ID NO: 1-3, or has 80% homology thereto, with the proviso that the polypeptide having identity to SEQ ID NO: 1-3 must also have the ability to bind to a causative agent of a disease or disorder, wherein the causative agent has SOD activity. Thus, claim 45 as currently pending requires that the polypeptide be effective in treating a disease or disorder. Accordingly, those polypeptides that would not be effective in treating a disease or disorder are now outside of the claims, and the claims only relate to those diseases or disorders that have a causative agent having SOD activity. Thus, the pending claims do not encompass the treatment of any disease or disorder as alleged in the Office Action.

Furthermore, the specification teaches not only that Aβ possesses SOD activity (specification at page 2, lines 3-11), but also teaches disease that have been found to be linked to SOD activity (specification at page 2, lines 11-19), as well as screening methods for identifying agents of the present invention (see, e.g., specification at page 3, lines 2-12). Therefore, the application is clearly enabled. The breadth of the claims is supported by the specification, the level of one of skill in the art is high, the state of the art includes identification of diseases and disorders having SOD activity, Applicants have provided sufficient guidance to allow one of skill in the art to make and use the claimed invention, and any experimentation undertaken by the skilled artisan would be merely routine and thus would not qualify as "undue".

For all of these reasons, reconsideration and withdrawal of the enablement rejections under 35 U.S.C. §112, first paragraph, is respectfully requested.

Claims 26-39, 45 and 47 were rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement because the claims allegedly

contain subject matter which was not described in the specification in such a way as to reasonably convey that the inventors had possession of the invention at the time of filing. The rejection is respectfully traversed.

The Office Action indicates that the claims are to "structurally undefined and limitless peptides obtained through a very broadly defined method." Office Action at 6. Further, it is further alleged that terms such as "functional variants" or "peptidomimetics" are not defined in the specification nor are they provided any comprehensible boundaries. Applicants respectfully disagree.

Initially, it is noted that claim 26 has been cancelled herein. Thus, the rejection will be discussed as it applies to the remaining claims. Claims 28-39 and 45 are all dependent on claim 27, which recites a peptide comprising a sequence selected from SEQ ID NO: 1-3, or a functional variant thereof which is at least **80% identical** to the recited sequence and which retains its ability to bind to a causative agent of a disease or a disorder, said causative agent having SOD activity, and inhibit the causative agent's SOD and/or metal binding ability. Furthermore, claim 47 also requires that the polypeptide retains its ability to bind to a causative agent of a disease or a disorder, said causative agent having SOD activity, and inhibit the causative agent's SOD and/or metal binding ability

Thus, the claims have been amended herein such that they do not relate to "structurally undefined and limitless peptides" but rather claim peptides of a defined sequence or those having 80% homology thereto, provided that the polypeptide retains its ability to bind to a causative agent of a disease or a disorder, said causative agent having SOD activity. Indeed, the peptides of the present invention are defined in the pending claims not only by sequence, i.e., structure, but by their functionality, thus ensuring that those peptides encompassed by the pending claims are clearly defined and supported by the specification. The specification, in providing not only a sequence but the functionality of the peptides of the present invention, has provided amble support for the genus of peptides presently claimed.

Consequently, reconsideration and withdrawal of the written description rejection under 35 U.S.C. §112, first paragraph, are respectfully requested.

VII. THE ART REJECTIONS ARE OVERCOME

Claims 26-39 and 47 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Wakasugi et al. (1994). The rejection is respectfully traversed.

Applicants respectfully remind the Examiner that a two-prong inquiry must be satisfied in order for a Section 102 rejection to stand. First, the prior art reference must contain all of the elements of the claimed invention, *see Lewmar Marine Inc. v. Barient Inc.,* 3 U .S.P.Q.2d 1766 (Fed. Cir. 1987), and, the single prior art reference must contain an enabling disclosure, *see Chester v. Miller,* 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990).

The Office Action indicates that Wakasugi et al. relates to a peptide with 58% identity to the peptide of SEQ ID NO: 3.

The pending claims are directed towards a peptide comprising a sequence selected from SEQ ID NO: 1-3, or a functional variant thereof which is at least **80% identical** to the recited sequence and which retains its ability to bind to a causative agent of a disease or a disorder, said causative agent having SOD activity, and inhibit the causative agent's SOD and/or metal binding ability.

As Wakasugi et al. describes a protein having only 58% identity to SEQ ID NO: 3, Wakasugi et al. fails to teach each and every element of the claims as currently pending. Thus, the reference fails under Section 102.

Consequently, reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) is respectfully requested.

REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, prior to issuance of any paper other than a Notice of Allowance, an interview, is respectfully requested, with the Examiner and his supervisor, and, the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

CONCLUSION

In view of the amendments, and remarks herein, the application is in condition for allowance. Reconsideration and withdrawal of the rejections of the application, and prompt issuance of a Notice of Allowance, is respectfully requested.

Respectfully submitted,
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